

Sample Collection and Processing

ORDERING PROVIDER: Complete the test requisition form – please include all required information. The completed requisition form must include patient consent for sample acceptance.

Serum Separator Tube (SST) – containing Clot Activator and Polymer Gel (recommended)

1. 8.5 mL of whole blood is drawn into a vacutainer tube with clot activator and polymer gel, mixed pursuant to tube specifications.
 - Example: If using a serum collection device. Follow manufacturer’s instructions for serum separation. Serum from non-SST/no gel barrier tubes **MUST BE** transferred to a Cryo tube and shipped frozen to be accepted for testing.
2. After collection of whole blood in the tube, immediately and gently invert the tube 8–10 times.
3. After mixing, the whole blood sample may be stored up to six (6) hours at room temperature until centrifugation, but no more than 2-3 hours is recommended.
4. Minimum clotting time of 30 to 60 minutes or as recommended by manufacturer should elapse prior to placing the collection tube in the centrifuge.
5. The tube is centrifuged at 2000xg for 10 minutes. Refrigerated (2-8°C) centrifuge is preferred.
6. Ensure serum is separated from the clot.

	Refrigerated Storage and Shipping
Collection Instructions	Following serum separation, refrigerate collection tubes vertically. Transfer serum to provided Cyro tubes by decanting or pipette. Cryo tubes are labeled with patients first name, last name, and DOB consistent with requisition form. Ensure two distinct identifiers along with all patient information (e.g., DOB, MRN).
Time from Collection & Centrifugation to Storage	2-3 hours, no more than 6 hours

COLLECTING SITE: Use either the provided shipping materials or provide your own materials to package the sample, which should include labeled collection tube or Cryo tubes with serum in a biohazard labeled bag and completed test requisition form in a plastic bag.

Sample Guidelines

Sample collection sites must follow the instructions below exactly as prescribed. **Any samples handled or stored outside of the prescribed conditions are not valid for testing.**

Samples should be collected and processed immediately following the guidelines in the table below.

	Refrigerated Storage and Shipping
Storage Temperature	2-8°C
Shipping Condition	Minimum of 2 frozen cold packs
Minimum Aliquot Volume	0.5 mL
Time from Collection to Arrival at Quanterix	7 days
Shipping days	Monday through Thursday

DO NOT SHIP SAMPLES ON DAYS PRECEDING A HOLIDAY.

Sample Shipping Overview REFRIGERATED

- On the day of the shipment, ensure availability of pre-frozen ice packs (minimum of 24 hours) for each Styrofoam shipping container for packing and shipping. Place each collection tube into the provided biohazard bag containing absorbent pad. To protect during shipping, place the collection tube in the sealed biohazard bag. **Ensure two distinct identifiers along with all patient information** (e.g., DOB, MRN).

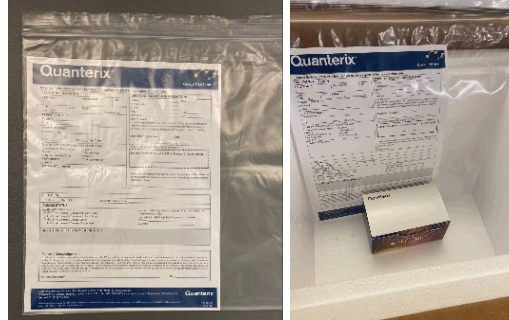


- Each insulated cooler MUST contain a minimum of two (2) pre-frozen ice packs to keep samples cold during shipment.

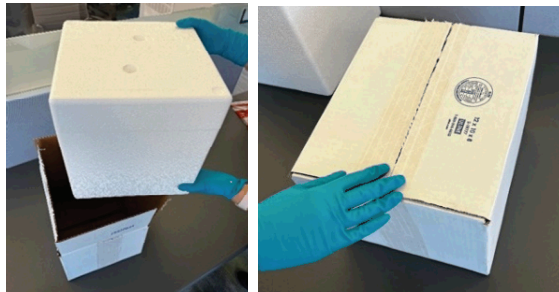


General Sample Shipping

1. Verify that a completed test requisition form, signed by the patient unless a separate trial consent is on file, has been placed in a plastic bag and is in the shipment container with the sample. **DO NOT PROCEED WITH SAMPLE COLLECTION UNTIL TEST REQUISITION IS VERIFIED BY ORDERING PROVIDER OR AUTHORIZED DESIGNEE.**



2. Secure the insulated cooler and ensure it is sealed.



Sample Shipping Process

The preferred shipper to Quanterix for testing is FedEx. Please fill the following information into the FedEx customer portal when creating a label:

Quanterix Corporation
Attention: Accelerator Laboratory
900 Middlesex Turnpike
Building #1
Billerica, MA 01821
USA

Enter your email onto the sender line and clinicalsupport@quanterix.com to the recipient line. This will allow Quanterix to track and process your sample shipments more efficiently. Please mark off the boxes to the right (a check mark will appear) which will tell FedEx what notifications to send. The notes field can be used for any pertinent text such as “12 samples in shipment.”

Format	Email address	Notification language	Shipment notifications	Tendered notifications	Exception notifications	Delivery notifications	Estimated Delivery notifications
Sender: Email (HTML)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recipient: Email (HTML)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Backer: Email (HTML)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other 1: Email (HTML)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other 2: Email (HTML)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Add personal message:

Not available with non-English characters

Quanterix Shipment Acceptance Criteria



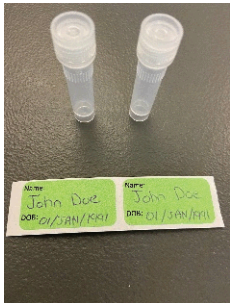


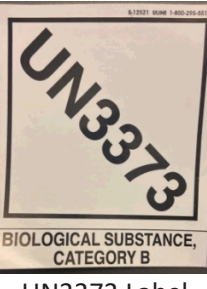

Quanterix requires the following conditions be met for shipments to be accepted for testing.

1. The samples will be verified to be maintained at cool temperature upon arrival at testing site, indicating they were packaged properly prior to transit.
2. The inside of the insulated cooler is free of spillage or leaks from samples.
3. The samples within the shipment match the completed test requisition form provided by the ordering provider.

If any of the above criteria are not met, the samples will not be processed, and the collecting site will be notified by the testing laboratory.

Basic Collection Material Contents

Inside Collection Material Box: SST Blood Collection Tube, Cryo tubes, Sealable Biohazard Bag with Absorbent Pad, Tube Stickers, Extra Zip Lock bag (for Test Requisition Form), UN 3373 Biohazard label.

 <p>Collection Material Box</p>	 <p>SST Collection Tube</p>	 <p>Cryo Tubes with labels displaying two patient identifiers</p>	 <p>Sealable Biohazard bag with Absorbent Pad</p>
 <p>Do Not Freeze Stickers</p>	 <p>UN3373 Label</p>	 <p>Ziplock bag for Test Req</p>	

Quanterix Collection Material Box Dimensions - Ref # 100403

- Outside (L x W x H): 5.1" x 3.15" x 2.56" (13cm x 8cm x 6.5 cm)

Return Shipper Dimensions

- Inside (L x W x H): 12" x 10" x 9" (30.48cm x 25.4cm x 22.86cm)
- Outside (L x W x H): 15" x 13" x 12" (38.1cm x 33.02cm x 30.48 cm)

Not Included with the collection material: Test Requisition Form, Sample Collection Instructions, Cold Packs and FedEx packing label